

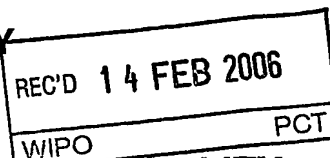
PATENT COOPERATION TREATY


PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)



Applicant's or agent's file reference NO 7444/WO		FOR FURTHER ACTION	See Form PCT/PEA/416
International application No. PCT/EP2004/007674	International filing date (day/month/year) 12.07.2004	Priority date (day/month/year) 15.07.2003	
International Patent Classification (IPC) or national classification and IPC A23L1/29, A23L1/052, A23L1/308			
Applicant NESTEC S.A.			
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 6 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> sent to the applicant and to the International Bureau a total of sheets, as follows:</p> <p><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>			
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the opinion</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input checked="" type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p>			
Date of submission of the demand 19.01.2005		Date of completion of this report 13.02.2006	
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465		Authorized Officer Rinaldi, F Telephone No. +49 89 2399-	

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Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
 - ☐ publication of the international application (under Rule 12.4)
 - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

Description, Pages

1-15 as originally filed

Claims, Numbers

1-15 as originally filed

- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing
3. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages
 - ☐ the claims, Nos.
 - ☐ the drawings, sheets/figs
 - ☐ the sequence listing (*specify*):
 - ☐ any table(s) related to sequence listing (*specify*):
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- ☐ the description, pages
 - ☐ the claims, Nos.
 - ☐ the drawings, sheets/figs
 - ☐ the sequence listing (*specify*):
 - ☐ any table(s) related to sequence listing (*specify*):

* If item 4 applies, some or all of these sheets may be marked "superseded."

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Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	
	No: Claims	1-15
Inventive step (IS)	Yes: Claims	
	No: Claims	1-15
Industrial applicability (IA)	Yes: Claims	1-15
	No: Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

Re Item V.

Cited documents

- 1 The following documents are referred to in this communication:
 - D1 : WO 02/39834 A (SCHIFFRIN EDUARDO ;SPIVEY KROBATH EVELYN (CH); NESTLE SA (CH); CAV) 23 May 2002 (2002-05-23)
 - D2 : US 2003/104033 A1 (LAI CHON-SI ET AL) 5 June 2003 (2003-06-05)
 - D3 : EP 0 721 742 A (CLINTEC NUTRITION CO) 17 July 1996 (1996-07-17)
 - D4 : EP 0 756 828 A (NUTRICIA NV) 5 February 1997 (1997-02-05)
 - D5 : US 6 200 950 B1 (MICHALSKI TOM ET AL) 13 March 2001 (2001-03-13)
 - D6 : WO 99/53777 A (CLAYTON DIANE ELIZABETH ;NOVARTIS NUTRITION AG (CH); LUSTENBERGER) 28 October 1999 (1999-10-28)
 - D7 : US 4 833 128 A (SOLOMON NEIL ET AL) 23 May 1989 (1989-05-23)
 - D8 : WO 03/053165 A (NAVARRO Y KOREN PETER ANTONIO ; NUTRICIA NV (NL); MINOR MARCEL (NL); D) 3 July 2003 (2003-07-03)
 - D9 : EP 1 314 362 A (SAMADHI BIOCYBERNETICS GMBH) 28 May 2003 (2003-05-28)

Clarity

- 2 The following clarity deficiencies were noted (Art. 6 PCT).
 - 2.1 A clarity problem arises from the wording of claim 1, as a powder is normally not measured in "ml". It is not unambiguously clear how to interpret a powdered composition having a definite energy density of .../ml and a dietary fibre content of .../100ml.
 - 2.2 Any composition having a ratio of 130-180 kcal per 2.5 g or more of dietary fibre is suitable to be reconstituted to the liquid disclosed in claim 1.
 - 2.3 The subject-matter of claim 6 is unclear, as a powder does not have a viscosity.
 - 2.4 The subject-matter of product claims 10-12 is considered to be related to non-therapeutic products. The same applies mutatis mutandis to the subject-matter of method claims 14 and 15.
 - 2.5 Following PCT-Guideline 5.23 the subject-matter of claims 10-12 will be interpreted as products suitable for providing the desired effect. In a claim directed to a product, features concerning its use are normally disregarded. A novel use of a composition does not make the composition as such novel.
 - 2.6 The subject-matter of claim 1 is not supported by p.3 §2.

Novelty

- 3 The subject-matter of independent product claim 1 and of independent method claims 13-15 does not fulfil the requirements of Art.33(2) PCT.
- 3.1 D1 renders available to the one skilled in the art compositions suitable for elderly patients and for restoration of gut integrity having 1.6 kcal/ml and up to 16.6g dietary fibres /100ml (claim 11; Example 1; p.1 l.1-p.3 l.7).
- 3.2 D6 discloses in Example 3 powdered compositions having a ratio of up to 0.18kcal each 2.5mg dietary fibre.
- 3.3 D7 (Example 1; col.2 l.1-18) discloses a dry food product which can be reconstituted to a drink, the dry food product comprising protein sources, carbohydrate sources, a fat source and dietary fibre in an amount of 2.5g per 167kcal. The viscosity of the reconstituted product is considered to be implicitly between 30-80 mPas.
- 3.4 D8 discloses a dry food product which can be reconstituted to a drink, the dry food product comprising protein sources, carbohydrate sources, a fat source and dietary fibre in an amount of more than 2.5g per 130kcal (p.7 l.6-p.8 l.3; examples 2 and 3). The viscosity of the reconstituted product is considered to be implicitly between 30-80 mPas.
- 3.5 D9 (Examples 1 and 2) discloses a dry food product which can be reconstituted to a drink, the dry food product comprising protein sources, carbohydrate sources, a fat source and pea dietary fibre in an amount of 2.5g per 176kcal. The viscosity of the reconstituted product is considered to be implicitly between 30-80 mPas.

Inventive step

- 4 The subject-matter of presently claimed does not involve an inventive step (Art.33(3) PCT).
- 4.1 D3 and D4 disclose independently from each other compositions having up to 1.8kcal/ml. The subject-matter of the present application differs only in that the dietary fibre content according to the present application is higher than the one disclosed in D3 and D4.
- 4.2 The objective problem is to provide compositions for the elderly providing good gut function.
- 4.3 In the first place it is known that the solution is provided by increasing the amount of dietary fibre. The idea of increasing the amount of dietary fibre is therefore not inventive, on the contrary, it appears to be rather a desideratum.
- 4.4 Additionally, D5 suggests the use of dietary fibres in fluid composition in an

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amount up to 12g/100ml (claim 9) for providing good functioning of the guts (col.1 l.1-col.2 l.31). The mixture of fibres to be used comprise oligosaccharides, soluble and non-soluble fibres in the amounts given in claims 1-4.

- 4.5 Similarly, in view of D2, a document disclosing complete fluid nutritional compositions containing up to 35g of fibres/L ([0002]-[0019] and [0050]-[0054]) the subject-matter does not appear to be inventive. D2 describes use of carboxymethyl cellulose, FOS, Fibrim, gum arabic and oat fibre (see table 4).
- 4.6 At present, the subject-matter of the depending claims is not considered to involve an inventive step.

Re Item VII

Certain defects in the international application

- 1 Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the documents D1-D9 is not mentioned in the description, nor are these documents identified therein.